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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,339	07/09/2001	Mai H. Nguyen	30448.78USU1	6039

7590 07/28/2004

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EXAMINER
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YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/901,339

Applicant(s)

NGUYEN, MAI H.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 15 and 16 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 1-7 and 15 is/are allowed.  
6) ☒ Claim(s) 8 and 16 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s). (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The prosecution is re-opened for the following reasons.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1-8, 15, and 16 are pending and under consideration.

#### ***Allowable Subject Matter***

As indicated before, claims 1-7, and 15 are allowed because the specification teaches good results at Table 1-4 for breast cancer diagnosis.

However, the indicated allowability of claims 8, and 16 is withdrawn in view of the newly discovered reference(s) to Sauter et al., Br J Cancer. 1999 Dec;81(7):1222-7. This rejection is made because the specification does not have any data of breast cancer prognosis. Rejections based on the newly cited reference(s) follow.

#### ***Claim Rejections - 35 USC § 103***

Claims 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen, M. of record (1997, Investigational New Drugs, 15:29-37, a copy provided with the Office action mailed on 09/13/2002) in view of Sauter et al., Br J Cancer. 1999 Dec;81(7):1222-7.

Claims 8, and 16 are interpreted as drawn to method of determining progress of breast cancer using the biomarker bFGF in a nipple fluid.

Nguyen teaches ,at Table 1 and pages 30-31, abnormal level of bFGF is detected in breast cancer patients, and also teach in the abstract that an attempt

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has been made to measure many cancer biomarkers in bodily fluids, also teaches that these cancer biomarkers are useful as a monitor of therapy.

Nguyen does not specifically teach a nipple fluid as a species of bodily fluids.

However, Sauter et al., teach at page 1222 "Present efforts to evaluate the breast directly either through evaluation of tissue or individual because the analysis of these specimens generally required an invasive procedure...Nipple aspiration has the attractiveness of quickly, painlessly, and non-invasively obtaining both breast epithelial cells (the cells at risk for transformation to breast cancer), as well as secreted proteins, which are concentrated in the fluid."

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use nipple fluid to determine the breast cancer biomarker, bFGF as taught by Nguyen secreted into urine. Since bFGF is a secreted protein, bFGF could be found in nipple fluid since Sauter et al., teach nipple aspirates containing secreted protein.

One of ordinary skill would have been motivated to use nipple aspirated to measure a breast cancer biomarker for monitor progress of breast given that advantage of using nipple aspirates (i.e. non-invasiveness of the procedure) as taught by Sauter et al.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone

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number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER

MISOOK YU, Ph.D.  
Examiner  
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